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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,343	05/07/2001	Juergen Roemisch	06478.1455	1124

22852 7590 09/30/2002

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/849,343	Applicant(s) ROEMISCH ET AL.
	Examiner " Neon" Phuong Huynh	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

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Art Unit: 1644

DETAILED ACTION

1. Claims 1-16 are pending.

2. Applicant's election with traverse of Group I, Claims 1-9 and 14-16, drawn to a stabilized protein preparation that read on the species of arginine as the amino acid, sucrose as the saccharide and FVIII (Factor VIII) is the blood clotting factor as the specific protein, filed 6/27/02, is acknowledged. The traversal is on the grounds that (1) it would not be undue burden on the Office to search the art concerning Groups I and Group II at one time even though it includes claims to independent or distinct inventions. This is not found persuasive because of the reasons set forth in the restriction mailed 5/7/02. Inventions of Groups I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the product as claimed can be used for making antibody and/or treating disease. Therefore, they are patentably distinct. Further, Groups I and II are drawn to different Class and subclass. A search of Group I would not encompass Group II and vice versa. It is a burden to search more than one invention. Therefore, the requirement of Group I and Group II is still deemed proper and is therefore made FINAL.

3. Claims 10-13 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected invention.

4. Claims 1-9 and 14-16 that read on the species of arginine as the amino acid, sucrose as the saccharide as the blood clotting factor and FVIII (Factor VIII) as the specific protein are being acted upon in this Office Action.

5. The disclosure is objected to because the arrangement of the specification does not follow the guidance. Please see Arrangement of the Specification indicated below.

6. The following guidelines illustrate the preferred layout for the specification of a utility application.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The recitation of "**more than** 1.5 g/ml" in original claim 5, line 2 has no support in the specification. It is suggested that applicant amend the specification to provide support for said phrase.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6, 8, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 4,623,717 (Nov 1986, PTO 1449).

The '717 patent teaches a method of making a stabilized protein preparation which protected against a loss of activity during pasteurization by adding stabilizers such as sucrose which is a saccharide (column 5, line 1, column 8, line 46-54, in particular) as a mixture with more than 0.5 mol/l of one or more amino acids such as arginine and contains no antithrombin III (See column 11, line 50-56, See claims of '717, in particular). The reference stabilized protein preparation contains protein selected from the list blood clotting factor such as Factor VIII (See column 8, line 53, in particular). The reference saccharide is present in the amount ranging from 0.8 g/ml, to 1.5 g/ml, which is at least 0.5 g/ml as recited in claim 3 (See column 9, lines 30-62, in particular). The reference teaches stabilized protein preparation contains one or more amino aids such as glycine, and arginine present in the range of about 0.05M to about 0.8 M (mol/l) (See column 5, line 41-44, in particular), which is more than 0.8 mol/l (M) as recited in claim 6. The reference preparation further subjected to viral inactivation by heat treatment such as 10 hours at 60 °C, which is within the claimed range of 40 to 95 °C for a period of 5 to 50 hours (See column 9, line 55, in particular) or heating at a temperature of about 60 to 75 C for a period of about 10 hours (See column 5, lines 54-57, in particular). The reference "about" expands the reference range of 0.8 M to read on the claimed more than 0.8 mol/l (0.8 M). Thus, the reference teachings anticipate the claimed invention.

10. Claims 1-2, 6, 8 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0077355 B1 (April 27, 1983, PTO 892).

The EP 0077355 B1 publication teaches a stabilized protein preparation such as one or more of blood clotting factors such as factor VIII, FVII, FX and their combination thereof (See page 14, claim 7 of EP 0077355 B1, in particular) which protected against a loss of activity during pasteurization by adding stabilizers such as one or more amino acid such as glycine, proline or other amino acid (See claim 11 of EP 0077355 B1, in particular) and one or more

saccharide such as non-reducing monosaccharide, oligosaccharide, mannitol, and sorbitol (See claim 12 of EP 0077355 B1, in particular). The reference amino acids are present in an amount of less than 1.0 mol/l, which is more than the claimed 0.8 mol/l as recited in claim 6 (See page 4, line 52, in particular). Claim 1 is included in this rejection because the reference teaches the other amino acids that are not glycine or proline and the reference preparation is free of antithrombin III (See page 14, claim 9 of EP 0077355 B1, in particular). The reference preparation includes heat treatment at 40 to 80 °C for a period of 5 to 200 hours (See claims 20-21 of EP 0077355 B1, in particular). The reference preparation includes filtered through a sterile filter (See claim 18 of EP 0077355 B1, in particular). Thus, the reference teachings anticipate the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 7, 9, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 4,623,717 (Nov 1986, PTO 1449) in view of US Pat No 4,960,757 (Oct 1990, PTO 1449).

The teachings of the '717 patent have been discussed supra.

The claimed invention as recited in claims 7 and 16 differs from the reference only that the preparation further comprises a soluble calcium salt in an amount of at least 0.5 mmol/l.

The claimed invention as recited in claim 9 differs from the reference only that the preparation further comprises a soluble calcium salt in an amount of at least 1.0 mmol/l.

The '757 patent teaches a stabilized protein preparation such as a pasteurized human fibrinogen or factor VIII (See column 2, line 48, in particular) which protected against a loss of activity during pasteurization by adding stabilizers such as sucrose which is a saccharide in the amount of 35 to 60 g/100 ml and amino acid such as glycine at 0.5 to 3 moles/l. The reference preparation further comprises soluble calcium salt such as 5 mmoles/l of $CaCl_2$, which is at least 0.5 or at least 1.0 mmol/l (column 2, line55-68, in particular). The reference stabilized protein preparation has good solubility and is useful for as an infusion solution in a very broad therapeutic field (See column 2, line 33-36, in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include soluble calcium such as calcium chloride ($CaCl_2$) as taught by the '757 patent in the stabilized protein preparation as taught by the '717 patent for a stabilized protein preparation which protected against a loss of activity during pasteurization by the addition of stabilizers which comprise any saccharide as a mixture with more than 0.5 mol/l of lysine or arginine, glycine and soluble calcium salt as taught by the '717 patent and the '757 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '757 patent teaches any stabilized protein preparation that has calcium salt (good solubility) is useful for as an infusion solution in a very broad therapeutic field (See column 2, line 33-36, in particular). In re Kerkhoven, 205USPQ 1069 (CCPA 1980), recognized that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having being individually taught in the prior art" (see MPEP 2144.06).

14. Claims 1, 3-5, 7, 9, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0077355 B1 (April 27, 1983, PTO 892) in view of US Pat No 4,623,717 (Nov 1986, PTO 1449) and US Pat No 4,960,757 (Oct 1990, PTO 1449).

The teachings of the EP 0077355 B1 have been discussed supra.

The claimed invention as recited in claim 3 differs from the reference only that the saccharide is in an amount of at least 0.5 g/ml.

The claimed invention as recited in claim 4 differs from the reference only that the saccharide is in an amount of at least 1.0 g/ml.

The claimed invention as recited in claim 5 differs from the reference only that the saccharide is in an amount of more than 1.5 g/ml.

The claimed invention as recited in claims 7 and 16 differs from the reference only that the preparation further comprises a soluble calcium salt in an amount of at least 0.5 mmol/l.

The claimed invention as recited in claim 9 differs from the reference only that the preparation further comprises a soluble calcium salt in an amount of at least 1.0 mmol/l.

The '717 patent teaches a method of making a stabilized protein preparation which protected against a loss of activity during pasteurization by adding stabilizers such as sucrose which is a saccharide (column 5, line 1, column 8, line 46-54, in particular) as a mixture with more than 0.5 mol/l of one or more amino acids such as arginine and contains no anti-thrombin III (See column 11, line 50-56, See claims of '717, in particular). The reference saccharide is present in the amount ranging from 0.8 g/ml, to 1.5 g/ml, which is at least 0.5 g/ml or at least 1.0 g/ml (See column 9, lines 30-62, in particular). The '717 patent teaches the advantage of the thermally stable and pasteurized protein preparation is useful for therapeutics with minimal loss of activity and substantially reduce the risk of being infected by the hepatitis virus (See column 4, line 13-23, in particular).

The '757 patent teaches a stabilized protein preparation such as a pasteurized human fibrinogen or factor VIII (See column 2, line 48, in particular) which protected against a loss of activity during pasteurization by adding stabilizers such as sucrose which is a saccharide in the amount of 35 to 60 g/100 ml and glycine at 0.5 to 3 moles/l as stabilizers and further comprises soluble calcium salt such as 5 mmoles/l of $CaCl_2$, which is at least 0.5 or at least 1.0 mmol/l (column 2, line55-68, in particular). The reference stabilized protein preparation has good solubility and is useful as an infusion solution in a very broad therapeutic field (See column 2, line 33-36, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include any saccharide in the amount of at least 0.5 g/ml or at least 1.0 g/ml or more than 1.5 g/ml as taught by the '717 patent and any soluble calcium such as calcium chloride ($CaCl_2$) as taught by the '757 patent in the stabilized protein preparation as taught by the '717 patent for a stabilized protein preparation which is protected against a loss of activity during pasteurization by the addition of stabilizers which comprise any saccharide as a mixture with

more than 0.5 mol/l of lysine or arginine, glycine and soluble calcium salt as taught by the EP 0077355 B1 patent, the '717 patent and the '757 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '717 patent teaches the advantage of the thermally stable and pasteurized protein preparation is useful for therapeutics with minimal loss of activity and substantially reduce risk of being infected by the hepatitis virus (See column 4, line 13-23, in particular). The '757 patent teaches any stabilized protein preparation that has calcium salt (good solubility) is useful as an infusion solution in a very broad therapeutic field (See column 2, line 33-36, in particular). In re Kerkhoven, 205USPQ 1069 (CCPA 1980), recognized that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having being individually taught in the prior art" (see MPEP 2144.06).

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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September 30, 2002

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